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Solid self-microemulsifying nutraceutical delivery system for hesperidin using quality by design: assessment of biopharmaceutical attributes and shelf-life

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Abstract

Aim: The present study endeavours to develop a solid self-microemulsifying nutraceutical drug delivery system for hesperidin (HES) using quality by design (QbD) to improve its biopharmaceutical attributes.

Methods: A 3^2 full factorial design was employed to study the influence of factors on selected responses. Risk assessment was performed by portraying Ishikawa fishbone diagram and failure mode effect analysis (FMEA). The *in vivo* antidiabetic study was carried on induced diabetic rats.

Results: The optimised liquid SMEDDS-HES (OF) formulation showed emulsification time (Y_1) = 102.5 ± 2.52 s, globule size (Y_2) = 225.2 ± 3.40 nm, polydispersity index (Y_3) = 0.294 ± 0.62, and zeta potential (Y_4) = -25.4 ± 1.74 mV, respectively. The solid SMEDDS-HES (SOF-7) formulation was characterised by FTIR, PXRD, DSC, and SEM. The shelf life of SOF-7 was found to be 32.88 months. The heamatological and histopathological data of diabetic rats showed prominent antidiabetic activity.

Conclusions: The optimised formulation showed improved dissolution, desired stability, and promising antidiabetic activity.

Keywords: Hesperidin; failure mode effect analysis; quality by design; risk assessment; self-microemulsifying drug delivery system; shelf life.

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